

The decade of the sixties in the *Journal*

Those were tumultuous times for the practice of medicine!

The original paper, "The Relative Value Studies: Fixed conversion vs. customary fees" was written 25 years ago in Vol 26, No 2 November-December 1966.. The reasons for the changes in the practice of medicine are well spelled out in the article.

The changes that have occurred since then were largely predicted by this article. HMOs and PPOs have proliferated. Medicare is about to impose a relative value scale of payments. HMSA is set to follow with a payment schedule modeled on that of Medicare.

Medicine is changing, in large part, because of its high cost. It now represents about 12% of the GNP. Yet many of the causes of health-care cost escalation are not within the physician's control. Paperwork needed to fill out forms and to prove compliance has increased. Staff shortages in the healthcare field have caused salary escalations. The legal system is increasing costs by causing defensive medicine. Families still want "everything possible" done for their sick or dying relatives "regardless of the cost." Changing technology allows much to be done for an individual patient, but the cost can be very high.

No one can really predict exactly what the practice of medicine will be like 25 years from now. Ultimately, it is society that determines what it expects from medicine and how much it is willing to pay.

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*... a long-time employee of the California Medical Association
foresees tumultuous times for the practice of medicine*

The Relative Value Studies: Fixed conversion vs. customary fees

Robert L. Thomas

Health care legislation, technological advances, increases in biological knowledge, better health and increasing longevity of people, changing patterns of professional activity, and changes in the structure and function of medical institutions are among the factors involved in the changes occurring in the character of the practice of medicine.

As the effectiveness of medicine increases, medical care is being considered by many people more and more to be a basic right of everyone and the concept of "separate but equal" is recognized as unsound.

The effectiveness and economy of medical services, both in manpower and in costs, are increasingly recognized as a con-

cern of the public, as well as of the physician and the patient.

Government regulations

Within the framework of federal and state health care legislation passed in the last 2 years, government has generally left "the delivery of medical care" alone. PL 89-239, the Heart Disease, Cancer and Stroke legislation, promises to accomplish its ends "without interfering with the patterns, or the methods of financing of patient care or of professional practice, or with the administration of hospitals." PL 89-97, the Medicare Law, goes a step further by promising that no federal official shall be permitted "to exercise any supervision or control over the practice of medicine or the manner in which the services are provided."

These are fine, well-intended phrases; but what about impact, regulations, corresponding changes in attitudes and direction?

Permit me to quote from an April 18, 1966, memorandum prepared by the Surgeon General of the United States Public Health Service to the Secretary of the Department of Health,

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Read before the Western Conference of Foundations for Medical Care,
Honolulu, June 21, 1966.

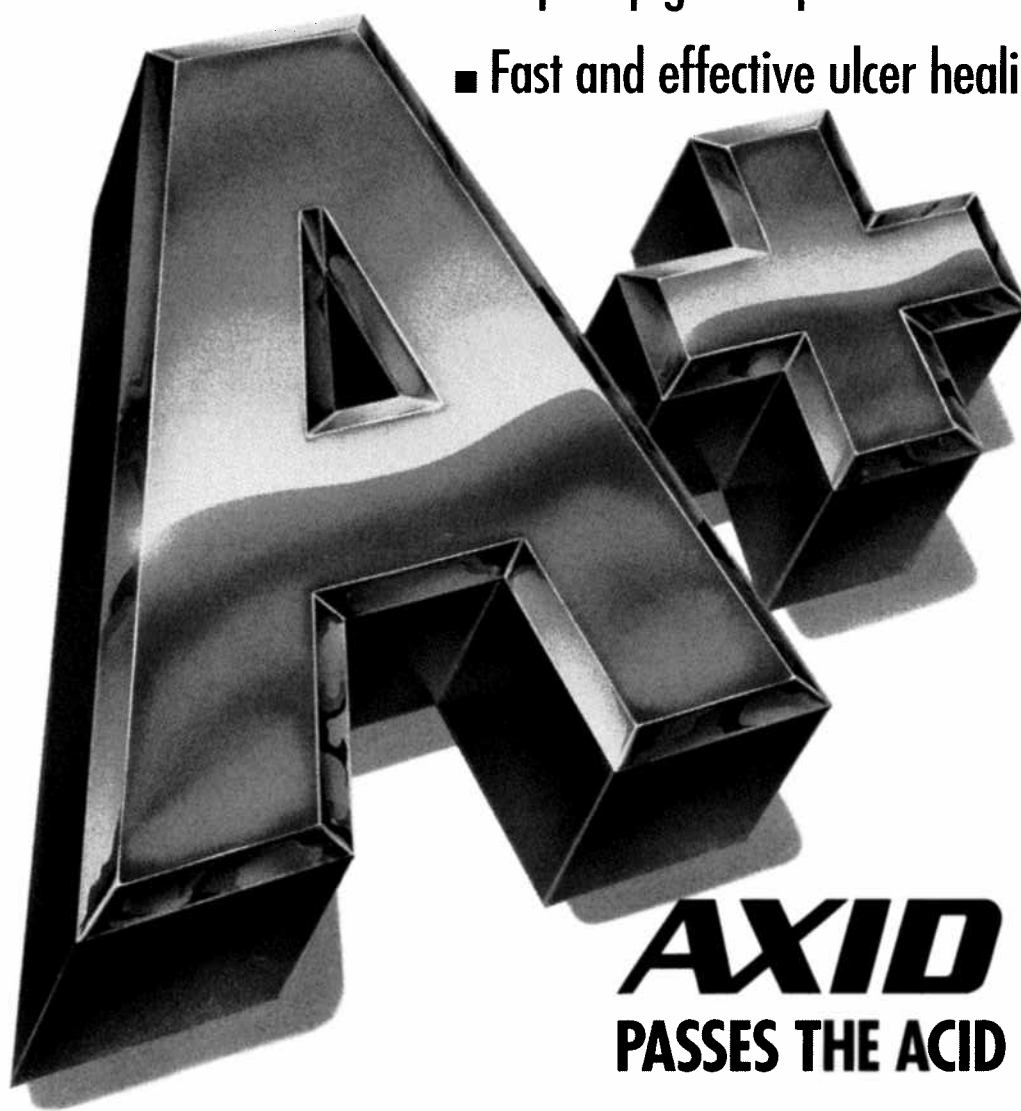
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Indications and Usage: 1. *Active duodenal ulcer*—for up to 8 weeks of treatment. Most patients heal within 4 weeks.

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2. Dosage should be reduced in patients with moderate to severe renal insufficiency.

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Drug Interactions—No interactions have been observed with theophylline, chlorazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450 enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increased serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A 2-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a 2-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 380 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a 2-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in 1 fetus, and at 50 mg/kg, it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in 1 fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Studies in lactating women have shown that 0.1% of an oral dose is secreted in human milk in proportion to plasma concentrations. Because of growth depression in pups reared by treated lactating rats, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Healing rates in elderly patients were similar to those in younger age groups as were the rates of adverse events and laboratory test abnormalities. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of varying durations included almost 5,000 patients. Among the more common adverse events in domestic placebo-controlled trials of over 1,900 nizatidine patients and over 1,300 on placebo, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common with nizatidine. It was not possible to determine whether a variety of less common events were due to the drug.

Hepatic—Hepatocellular injury (elevated liver enzyme tests or alkaline phosphatase) possibly or probably related to nizatidine occurred in some patients. In some cases, there was marked elevation (>500 IU/L) in SGOT or SGPT and, in a single instance, SGPT was >2,000 IU/L. The incidence of elevated liver enzymes overall and elevations of up to 3 times the upper limit of normal, however, did not significantly differ from that in placebo patients. All abnormalities were reversible after discontinuation of Axid. Since market introduction, hepatitis and jaundice have been reported. Rare cases of cholestatic or mixed hepatocellular and cholestatic injury with jaundice have been reported with reversal of the abnormalities after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in 2 individuals administered Axid and in 3 untreated subjects.

CNS—Rare cases of reversible mental confusion have been reported.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to nizatidine. Impotence and decreased libido were reported with equal frequency by patients on nizatidine and those on placebo. Gynecomastia has been reported rarely.

Hematologic—Fatal thrombocytopenia was reported in a patient treated with nizatidine and another H₂-receptor antagonist. This patient had previously experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

Hypersensitivity—As with other H₂-receptor antagonists, rare cases of anaphylaxis following nizatidine administration have been reported. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever, and nausea related to nizatidine have been reported.

Overdosage: Overdoses of Axid have been reported rarely. If overdosage occurs, activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis does not substantially increase clearance of nizatidine due to its large volume of distribution.

PV 2091 AMP
[09/11/90]

References

1. Data on file, Lilly Research Laboratories.
2. *Scand J Gastroenterol*. 1987;22(suppl 136):61-70.
3. *Scand J Gastroenterol*. 1987;22(suppl 136):47-55.
4. *Am J Gastroenterol*. 1989;84:769-774.

NZ-2943-B-149347

Additional information available to the profession on request.



Eli Lilly and Company
Indianapolis, Indiana
46285

Education and Welfare; the subject: "Reorganization of the Public Health Service."

... I feel that the time is now ripe for a definitive statement of our aims and the organizational structure which will, in my judgment, serve them best. This memorandum is designed to constitute such a statement.

My fundamental thesis is that the health of the American people, *in its totality*, shall be the overriding concern of the Public Health Service and the measure of our success or failure. Our ultimate commitment is not to agencies or institutions, but to people. In this context the Surgeon General should be the individual to whom the public may turn when their expectations for health care are not being fulfilled.

The Service would welcome this assumption of central responsibility for health on behalf of the people.

The memo continues to describe a proposed organizational plan consisting of 8 major components, as follows:

Bureau of Health Services
Bureau of Health Manpower
Bureau of Disease and Injury
Prevention and Control
National Institutes of Health
National Institute of Mental Health

and, reporting directly to the Office of the Surgeon General, the National Library of Medicine and the National Center for Health Statistics.

The memo continues:

The rapid growth of Federal involvement in health affairs has made our present organizational structure obsolete and dictated the need for reorientation. There is every reason to expect that this involvement will continue to grow and diversify. Therefore, any structure must be adaptable to change ...

Does this memo spotlight a "stage door Johnnie" or a "stand-in" waiting in the wings of the public stage?

The hospital

Let's examine more closely some of the changes and choices being brought about by these pressures and effects of regulations in view of our concern for high quality care, the continuation of prepaid medical care insurance, our concern over methods of physician remuneration, and our need to strengthen and maintain the tools, mechanisms, and techniques now available to the medical profession.

PL 89-97 has embodied in it concepts which may have a profound impact on the practice of medicine, the insurance industry and the methods of physician compensation.

In broad terms, this law establishes the hospital as the center of medical care for the community. It establishes methods by which standards of care can be enforced and quality of care evaluated and judged. It provides standardized definitions which now serve as a national mode of communication, for example, extended care facility, utilization review, prevailing charges, transfer agreement, and home health services, to mention only a few.

PL 89-97 establishes the premise of high level, centralized policy, leaving implementation to those who provide the care, yet establishing a secondary level of supervision to make sure various stipulated criteria are met by the providers. It places within the realm of reality, for 15 to 20% of the population, the meaning of many of the relatively new phrases and words in the medical and health planning vocabulary, such as, "broad

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spectrum of services," "continuity of care," "progressive care," "home care," "mainstream care" and "comprehensive care."

Fragmentation of practitioners into more specialties and subspecialties may be promoted by the Heart, Cancer and Stroke Program. At the same time, general practitioners, internists, and surgeons will receive the bulk of the increase in home, office, nursing home, and hospital care under PL 89-97. Ophthalmologists and urologists will also feel the impact of this newly released demand for services. Paramedical personnel will begin to face new and more demanding problems in education, striving for professional status, certification, and licensure.

The mobility of our population will probably add to the emphasis being placed on the hospital as a community health center; and provisions in the new law for outpatient and clinic diagnostic services may further increase this emphasis. Our present supply of health manpower will be used to its limits, and any shortages in such manpower may encourage greater numbers of people to turn to hospital emergency rooms and outpatient departments for immediate, necessary care. Physicians can respond to increased demands only to the limits of their human capacity. This fact alone may accelerate the movement into group practice by larger numbers of practitioners.

The hospital setting presents an area for some interesting speculation. Obviously, health facility planning must either develop real teeth, real community support, and real coordination, or bow to government control.

Hospital accreditation has been a voluntary effort. *Now*, the meaning of accreditation is assuming a somewhat different significance. The hospital medical staff must now show increasing proof that through its cooperative effort, it can and will assume responsibilities for education, quality control and, to a degree, evaluation of "physician obsolescence."

The physician must accept the evaluation of his colleagues, and unless his performance meets their combined standards, his privileges of practicing in the institution may be lost. It's possible; therefore, to view the hospital medical staff as becoming the *de facto* surveillance group of the community for physicians in hospitals, and the county medical society becoming the equivalent for physicians providing outpatient care.

Health insurance

All of these factors will have an impact on the costs of medical care and the way physicians are paid for their services . . . an impact with many good features, many bad, but definitely an impact of magnitude.

The most obvious implication is the elimination from the voluntary insurance market of about 10% of the population unless voluntary health insurance fills the gaps quickly. Future voluntary insurance programs are already being integrated with Medicare, as pension plans have been with Social Security benefits.

Also, it is only natural to expect labor and other employee groups to demand at least the same scope and type of benefits for the below-65 group as is now available to the retired. This

factor alone will increase the pressures from the insurance industry to cast aside caution and to rely on the standards being established by government in lieu of previous experience and underwriting principles.

A test of some traditional concepts regarding co-insurance and deductibles is in the offing; the insurance industry will, in my opinion, be compelled to follow the experience of PL 89-97. Voluntary prepaid medical care insurance must change from its primary emphasis on in-hospital coverage and join the movement toward coverage for total care of the patient; it must also — in the main — follow the concepts of customary, reasonable, and prevailing fees for physicians.

Employers and the insurance industry certainly must be looking at the cost control devices demanded by government in PL 89-97, and it seems reasonable to expect that industry will rely increasingly on services made available by the medical profession in identifying excessive hospital and nursing home utilization, unusual fees, unusual patterns of outpatient care, and fraud. Industry will also gain from the new emphasis by hospitals on standardized cost accounting.

It is interesting to speculate on the possible acceptance, at least in part, of the Australian system of making insurance available to all, or encouraging its acquisition, by combining the elements of partial payment by the patient and fee-for-service for the physician, with the entire system being underwritten, in part, by a tax-supported subsidy.

All that I have mentioned thus far focuses on the topic given to me for today. It is now obvious that —

- (1) A universal, single mode of communication, adapted to the electronic age and the needs of computers, is necessary.
- (2) Due to an accelerated social revolution, ever diligent, continuing efforts are necessary to codify in precise terms the various things a physician does or can do.
- (3) The government has honored, at least temporarily, the claim of the medical profession that it is truly a profession, capable of self-determination and self-discipline.
- (4) The government has broken away from the static fee-schedule concept and has acknowledged the system of free enterprise, supply and demand, marketplace method of establishing physicians' fees on the basis of the customary, reasonable, and prevailing charges.
- (5) The fee-for-service concept is also to be given a fair trial — in full public view. The basis for this comparison is built into PL 89-97, with special provision made for payment to closed panel group practice plans on a reasonable cost basis.

Relative value studies

The RVS is, in my opinion, one of the major tools available to the profession in meeting many of these challenges. There is not available, at this time, any other device which meets the communication needs of common coding and terminology of medical procedures; nor is there any better tool, readily available to physicians and administrators, which provides guidelines for determining the approximate or appropriate relationships between services performed by physicians.

The problem is to keep the document current, to redefine terms, to correct or to clarify definitions of medical procedures as these change. Let me cite 1 or 2 examples where change may already be indicated: The RVS Surgical Section has many unit values based on the global fee concept. With the expanding development of progressive levels of care, such

as Hospital, Extended Care Facility, and Home Care; with dietitians, physical therapists, and visiting nurses requesting instructions, clearances, and directions; and with periodic recertification of need, the physician's sphere of responsibility is increased, his time more divided between facilities and personnel without any recognized need for concurrent change in payment.

The use of the RVS by some carriers and county society review committees, in the evaluation of customary and reasonable fees, may raise the issue of dual schedules or differential fees for various specialties. The RVS does not acknowledge the age-old argument about dual fee schedules. The theory embodied in the RVS is that equality is an inherent element in the assignment of unit values, since specialists determine unit values for procedures which *only* they can perform, while other units reflect the concept of equal payment for equal service regardless of specialty. This concept certainly seems sound to me, especially where peer judgments control the extent of a physician's professional freedom within the hospital setting. If these factors are found to have a serious effect upon the RVS, it will, of course, have to respond to new demands of medical practice.

After nearly 13 years of effort, the CMA has not produced a *perfect* document, nor does it ever expect to be able to do so. How can an RVS be flawless, in view of changes in medicine which are so complex that even general predictions are impossible? But is there any better tool available at this point in time?

Currently, 24 state medical societies and 6 national specialty organizations, whose members constitute more than half of all physicians in private practice, have adopted an RVS. The AMA is now working on a national listing of coding of procedures, using its booklet, "Current Procedural Terminology," as a basis. It is being designed for use by physicians, insurance carriers, and government. This new approach, too, has its shortcomings, because any document which is national in scope will lag more in reflecting change than a state-based counterpart.

The intermediary

PL 89-97 provides the profession with an opportunity to retain a system of payment which physicians believe in, accented by the stated desire of the U.S. Senate Finance Committee that the government *not deal directly* with physicians — but through intermediaries. That system embodies payment based on fee-for-service and interpreted on the basis of customary, reasonable, and prevailing charges; with geography, specialty, and unusual problems all taken into consideration.

An additional factor is the acknowledgement by the Federal Government and Congress that a physician's customary charge is not necessarily a static amount; that he may alter his charges at will, provided he does so for all of his patients; and that in cases commanding a higher than usual fee, that the circumstances be reviewed and recommendations made by his peers.

I have mentioned the government's recognition of the practice of medicine as a profession. Just what is a profession? Licensure by a public body is, of course, an accepted standard

but there are other standards, too.

A profession is a group of learned people who adopt higher than normal standards of behavior and accept the responsibility of self-discipline. It also is a group willing and able to exercise reasonable judgments and self-restraint, to be dedicated to a cause, and to accept public responsibility for its activities.

In the implementation of PL 89-97, the medical profession is being asked to assume the authority which is necessary to meet its responsibilities.

In granting the profession most of its time-honored principal elements considered necessary for the provision of high quality care, acceptance is now a public matter of:

1. Free choice of physician.
2. Fee-for-service reimbursement.
3. Customary and reasonable fees.
4. Preservation of the dignity of the patient, and
5. Freedom from interference by government in the delivery of care.

These are all factors repeatedly stated to be necessary for a free profession to progress and to provide a continuous high level of care.

Terminology

Yet only a few days ago, a physician said to me, "You know, I'd rather be paid on a schedule based on the 1964 RVS with a \$6 factor than on the usual and customary basis!"

After I'd recovered sufficiently, I asked the obvious "Why?"

His answer was even more surprising. "Because," he said. "I will have no responsibilities under a schedule." During the same day, another physician told me that he would rather be paid on the basis of usual and customary charges than on a fee schedule based on the 1964 RVS with a \$10 unit conversion factor. In response to my question, "Why?", he answered, "It's the principle involved." Two different approaches, with a real potential for conflict within the profession!

Join me while I examine, in part, factors included in both statements:

Let's start with the key portions of the fee definitions used in PL 89-97:

Customary — "the customary charge for similar services generally made by the physician."

Prevailing — "the prevailing charges in the locality for similar services."

Reasonable — "in determining the reasonable charge for a physician's services, there shall be taken into consideration the customary charge for similar services generally made by the physician as well as the prevailing charges in the locality for similar services."

The term "prevailing" has other legal definitions as well. This one resulted from a court decision in Baltimore: "The word prevailing is properly construed as meaning prevalent, most general, common, predominant as current, and not as meaning *either* an average or a median."

Obviously, there are several important words in these definitions that to me can never be related to any fixed fee schedule, no matter what the value of the conversion factor. To be specific: The definitions relate to each individual physician, not all physicians, *in toto*. This means that there can be recognition for training, years of experience, time spent with a

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patient or difficult case, variations in overhead and variations between people. The definitions indicate that there is a range of fees which is related to the norms of a community. Certainly, the "professor type" care is not usual within a community — nor is bargain-basement-type care. Fees and patterns of care should be compared, viewed or evaluated on the basis of *local customs* within a geographic locality. There is within each community a range where fees are reasonable; there is also a level at which a fee is unreasonable. Lastly, no physician is bound by the units in the RVS, since they represent averages or norms and are recognized as guides or as a means of communication only.

There are, however, some problem areas in the usual and customary fee approach. For instance:

- (1) The community range of reasonable charges may become narrow, with the elimination of highs and lows, and tend to become a spongy type of self-imposed fee schedule. True, *except* that government, in PL 89-97, has stated that the physician's fee is recognized to be *not* static, hence the reasonable range is moving, dynamic and flexible, not fixed.
- (2) Physicians must accept great and grave responsibilities to assure the success of this approach and to meet adequately the public trust now placed in their hands.
- (3) No matter what the situation, there must always be both fiscal controls and fiscal standards established and maintained by someone. This fee approach requires that physicians do this by sitting in judgment of their peers and by exercising reasonable restraint.
- (4) The usual-and-customary-fee approach embodies ethics, law, and professional responsibility.
- (5) The usual-and-customary approach can be very difficult for a carrier or fiscal agent to administer.

But, are these hurdles too much to expect a profession to overcome?

Fee schedules

Let's take a look at fee schedules. One good feature which I recognize is that a schedule will help in estimating and controlling total costs. This is of real value when the profession, by mutual agreement, seeks ways to make care available to families of low income. The Blue Shield concept is based on this approach, as are many of the Foundation programs. This feature has demonstrated its value to one method of making medical insurance meaningful for millions of people.

Self-administered health and welfare plans also need some assurances of cost controls. In the absence of wide experience with usual and customary fees, the financial soundness of these types of arrangements needs to be protected.

But what are some of the bad features?

- (1) A schedule pays all physicians equally without regard to the true value of their services in the open competitive market place or without regard to the quality of care provided. There is no supply and demand relationship to determine the marketable sales price of a commodity.
- (2) A fixed schedule is not resilient and is slow to respond to changes in local economic conditions.
- (3) A schedule tends not to recognize any variation between location of practice such as urban, rural, downtown versus main street, or community patterns, type or scope of services demanded or needed by the patient.
- (4) The fee level of a schedule is based on the economic situation of a particular employer or segment of the population — mostly a by-product of labor-management negotiations for employee fringe

benefits.

- (5) A schedule can be unreasonable — either high or low — and can cause either an inflation of costs to others or poor, bargain basement care for bargain basement fees, even though this latter is recognized as unsound and against medical policy.
- (6) A schedule does not permit a physician to determine what he considers to be a fair profit.
- (7) A schedule may hinder the scope of care a physician may render a particular patient without financial subsidy or possible loss to the physician.

In California, we have been fortunate in getting the same fee language used in PL 89-97 put into our state law implementing Title XIX, which became effective on March 1. It calls for customary, reasonable, and prevailing fees. At the outset of the program, it was necessary for the state designated administrative agency, our Blue Shield Plan, to set up some claims review mechanisms, so that claims falling into approximately the top third of a community range would be subject to an administrative and professional review.

CMA asked that CPS use, *as the beginning point for this review*, a countywide coefficient on the 1964 RVS for each county within the state. These figures were derived from a 1963 statewide survey of fees and adjusted for cost of living increases through 1965. After nearly 4 months of experience with the customary-and-prevailing fee application, the results, in my opinion, prove that this concept is workable and sound, provided that members of the medical profession, acting through county medical society professional review committees, shoulder their responsibilities faithfully and face up to problems squarely.

To emphasize this point, since March 1, CPS has paid a total of 323,951 claims from physicians. Of that number, approximately two-thirds fell within the county-wide guidelines and have been paid without the necessity of special review. Of the other third, it has been estimated that less than 5% were referred to county society review committees for study and recommendation on the reasonableness of the fees or on patterns of care.

To me, the real major difference between a schedule and the usual-customary approach is the question of standards. Who establishes them? Who enforces them and who is responsible for their modification?

Professional obligation

Now that PL 89-97 has suddenly thrust on the profession this new responsibility and authority — which it pleaded for — what will happen if the profession fails to meet its professional obligations? Surely, a loss of prestige and a loss of public trust and confidence. The profession of medicine stands to lose its effective voice and, in the public eye, forever relinquish its rights to a second chance or to valid consideration.

If, on the other hand, the public trust is upheld, it is reasonable to expect that the concept of usual and customary fees will become an accepted fact of life for most medical care programs.

The Foundations for Medical Care have, I believe, an exceptional opportunity to assert their leadership. More than ever before, claims review, outpatient utilization review, and cost and quality controls depend on effective interpretation of local customs and patterns. Here is your opportunity to prove

that the know-how gained from other programs has qualified you to lead by example and to teach or help others who may weaken and fall by the wayside.

In Eric Fromm's book, *Escape from Freedom*, he analyzes man's desire for freedom, and his flight, when it is once achieved, from its responsibilities. In discussing the problem of freedom, in its two-fold meaning, Doctor Fromm stated that freedom *from* the traditional bonds of medieval society, though giving the individual a new feeling of independence, at the same time made him feel alone and isolated, filled him with doubt and anxiety, and drove him into new submission and into a compulsive and irrational activity.

Doctor Fromm asks in his book, "can freedom become a burden, too heavy for man to bear, something he tries to escape from? Why then is it that freedom is to many a cherished goal and for others a threat?"

The medical profession must not seek to escape from its new found freedom, even though its burdens are great and its responsibilities tremendous; neither must this freedom be abused.

I firmly believe that if the profession does not fulfill the public trust and confidence as exemplified in PL 89-97, it will enter a new and long period of submission.

Responsibility always carries with it difficulties, yet determination and purpose can usually prevail.

An appropriate conclusion should be to quote, in Hawaiian, some great pearl of wisdom. Unfortunately, I neither speak the native tongue nor do I have a pearl. I can, however, say that I welcome this opportunity to contribute to the *customary* confusion, *prevailing* turmoil, and *reasonable* ferment.



"No, Mrs. Adams, you've got it wrong — the ailment was imaginary, the bill is real."

YOCON[®]

YOHIMBINE HCl

Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubiaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon[®] is indicated as a sympatholytic and mydriatic. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.^{1,2} Also dizziness, headache, skin flushing reported when used orally.^{1,3}

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

How Supplied: Oral tablets of Yocon[®] 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

References:

1. A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

Rev. 1/85



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